

Clean version of amended claim 2

- a2
- 2 (Amended) A hybrid medical implant comprising an elastomeric, nonbioabsorbable core portion having an outer surface and a bioabsorbable portion affixed to said outer surface of said core portion wherein said outer surface comprises a plurality of particles of a bioabsorbable material embedded in a nonbioabsorbable elastomeric substrate and wherein said outer surface of said hybrid medical implant has an irregular topography.

STATUS OF THE CLAIMS

Claims 1-13 are pending in the application.

Claims 1,2,5,6,10 and 13 were rejected under 35 USC§102(b) as being anticipated by Berman '366.

Claims 1-6 and 10-13 were rejected under 35 USC§102(e) as being anticipated by Corbitt, Jr. et al. '045.

Claims 1,3,5,7,9, 10 and 13 were rejected under 35 USC§102(b) as being anticipated by Naficy '998.

Claim 8 was rejected under 35 USC§103(a) as being anticipated by Berman '366 in view of Naficy '998.

Claim 12 was rejected under 35USC§112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention.

Claims 1,3,5,7,9,10,12 and 13 are canceled by this Amendment A.

Claim 2 is amended by this Amendment A.

Following entry of this Amendment A, Claims 2 (Amended), 4,6,8 and 11 remain pending in the application.

REMARKS

SUMMARY OF THE INVENTION

A hybrid medical implant having a biocompatible, nonabsorbable core portion and a textured outer surface portion overlying the core portion wherein a portion of the outer surface portion is bioabsorbable. The hybrid implant is useful as a prosthesis for tissue augmentation and/or reconstruction. The core portion of the implant includes a body

formed from a nonabsorbable, biocompatible implantable material such as silicone or urethane elastomer. The core portion may be either a solid body, a viscous gel body or a fluid-filled shell. The textured outer surface portion envelops the core portion and presents an irregular, textured surface to the exterior environment. The irregularities in the outer surface are due to a plurality of bioabsorbable particles embedded in a nonbioabsorbable elastomer comprising the outermost surface of the implant and projecting outwardly from the outermost surface of the nonbioabsorbable elastomer.

The Rejection Under 35USC§102

Claims 1,2,5,6,10 and 13 were rejected under 35 USC§102(b) as being anticipated by Berman '366. Claims 1-6 and 10-13 were rejected under 35 USC§102(e) as being anticipated by Corbitt, Jr. et al. '045, and Claims 1,3,5,7,9, 10 and 13 were rejected under 35 USC§102(b) as being anticipated by Naficy '998. Briefly, Naficy '998 and Corbitt, Jr. et al. disclose an implantable prosthetic device comprising a nonbioabsorbable core enveloped by a bioabsorbable (or reabsorbable) shell. The shells in both Naficy and Corbitt, Jr. et al. are entirely absorbable. Corbitt, Jr. et al. (Col 2, lines 42-46) discloses an outer shell comprising a bioabsorbable fiber woven to form a mesh, or, in the case of Naficy, (Col. 3, lines 57-68) the nonabsorbable core is enclosed within a bioabsorbable shell that is spaced from the core. In Berman, the outer surface of the implant is entirely bioabsorbable and the entire body of the prosthesis (i.e., the outer surface and the underlying core) comprises a bioabsorbable material.

In contrast, the present invention discloses and claims a medical implant comprising a fluid-filled, nonbioabsorbable core enveloped by an outer shell that comprises a flexible nonbioabsorbable elastomer, such as silicone elastomer, wherein the

nonbioabsorbable elastomer has a plurality of bioabsorbable particles embedded therein and projecting outwardly from the outer surface of the outer shell and presenting an irregular topography. Support for the presently claimed subject matter is provided in the specification on page 13, lines 3-16. The method disclosed for adhering bioabsorbable particulates to an outer shell having an uncured silicone outer surface provides a medical implant having the structural features recited in Claim 2 (Amended).

In order for a patent to qualify as a reference supporting a §102 (b) rejection, it must disclose each and every limitation of the rejected claim. It is settled that even only slight differences between the compared inventions prevent a rejection based on lack of novelty under §102. Anticipation under 35 USC§102 requires that the cited references demonstrate each and every element of the claimed invention. In view of the differences between the elements of the present invention and those of the prior art presented herein, it is requested that this rejection be withdrawn.

The Rejection Under 35USC§103

Claim 8 was rejected under 35USC§103(a) as being unpatentable over Berman IVO Naficy. The Examiner argues that while Berman does not disclose a silicone core portion, but otherwise meets the present invention and that it would be obvious to make the claimed invention when Berman is viewed in the light of the Naficy disclosure. As noted above, neither Berman nor Naficy teaches a medical implant wherein the outer shell comprises a plurality of bioabsorbable particulates embedded in a cured silicone elastomer to present a textured outer surface having an irregular topography. The presently claimed invention discloses an outer shell wherein a portion of the shell is nonbioabsorbable and has a plurality of bioabsorbable particles embedded therein and projecting outwardly therefrom.

In considering the question of obviousness of the claimed invention in view of the prior art relied upon, the applicant submits that the test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. A *prima facie* case of obviousness is established when the teachings of the prior art itself would appear to have suggested the claimed subject matter to one of ordinary skill in the art.

The law requires an applicant to show only that the claimed combination of structure is non-obvious in view of the prior art under Deere. In fact, the CAFC has made it clear that an invention need not operate differently than the prior art to be patentable, but need only be structurally different.

In summary, under Deere (*op.cit*), and as set forth in *MPEP* §706.02, to establish a *prima facie* case of obviousness of a particular claim, the Patent Office must :

- (a) set forth differences in the claim over the applied references;
- (b) set forth the proposed modification of the references which would be necessary to arrive at the claimed subject matter; and
- (c) explain why the proposed modification would be obvious.

To satisfy step (c), the Patent Office must identify where the prior art provides a motivating suggestion to make the modifications proposed in step (b). In the present instance the combination of elements; specifically, a medical implant having a nonbioabsorbable core and a hybrid outer shell enveloping the core, wherein the hybrid outer shell comprises a nonbioabsorbable elastomer having a plurality of bioabsorbable particles embedded therein, and projecting outwardly therefrom, as recited in independent claim 2, are different from the elements in the prior art and, moreover, are not suggested by

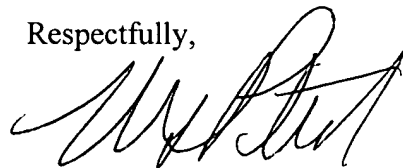
the prior art. In view of these clarifications regarding the difference between the elements of the present invention and the prior art it is requested that this rejection be withdrawn.

The Rejection Under 35USC§112

The claims of the application have been carefully reviewed in light of the objections raised by the Examiner in the outstanding Office Action. Specifically, Claim 12 has been canceled. Applicant respectfully submits that the amended claims overcome the rejections under 35USC§112, and an indication to this effect is respectfully requested.

Entry of this amendment, reconsideration, favorable action and early allowance and publication of this application are respectfully requested. If there are any minor matters remaining, it is respectfully requested that the examiner contact the undersigned by phone so that possible minor changes may be discussed in order to expedite the prosecution of this case.

Respectfully,



Michael G. Petit, Reg. No. 30,795

P. O. Box 91921

Santa Barbara, CA 93190-1929

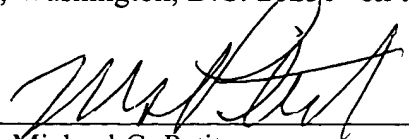
Tel: 805-563-6556/Fax: 805-563-6615

Certificate of Mailing

I certify that this correspondence will be deposited with the U.S. Postal Service as Express Mail (mailing label No.EV118367226US) with proper postage affixed in an envelope addressed to: "Commissioner of Patents and Trademarks, Washington, D.C. 20231" on the date below.

Date: December 27, 2002

by:



Michael G. Petit